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Docket No. 44342.013400

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Tohru FUSHIKI et al.

Date: February 8, 2002

#22
B.J
3/6/02

Serial No.: 09/367, 481

Art Unit: 1651

Filed: August 13, 1999

Examiner: Coe, S.

Title: ATHLETIC ENDURANCE INCREASING AGENT

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF UNDER 37 CFR 1.192

Sir:

This is an appeal from the final rejection of claims 24 to 31, 40 and 41, which was mailed on September 22, 2000, and pursuant to the Notice of Appeal mailed on September 7, 2001.

REAL PARTY IN INTEREST

The real party in interest for this appeal is Nippon Shinyaku Company, Ltd., of Kyoto 601-8550 Japan.

RELATED APPEALS AND INTERFRENECES

There are no related appeals or interferences connected with this appeal.

STATUS OF CLAIMS

Claims 24 to 31, 40 and 41 are pending in the application and stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 3,764,692 (Lowenstein) in view of Patent No. 5,536,516 (Moffett, et al.) and McCarty (45 Medical Hypotheses 247-54).

STATUS OF AMENDMENTS

An amendment to the claims was submitted by Appellant with the request that claims 32-39 be cancelled without prejudice or disclaimer of the subject matter recited therein, and that new claims 40 and 41 be added. In an advisory action, the Examiner indicated the amendment would be entered upon the filling of an appeal. Hence, the amendment should now be entered leaving claims 24 – 31, 40 and 41 on appeal before the Board.

SUMMARY OF THE INVENTION

The present invention relates to an exercise endurance enhancing composition, comprising as the active component (-) – hydroxycitric acid ("HCA") or a lactone or a salt form thereof (collectively referred to herein as "hydroxycitric acid compound"). (Spec., p. 1, l. 3-6). The invention addresses a problem among athletes concerning the improvement of athletic performance. (Spec., p. 2, l. 10-12; p. 11, l. 6-17, 27-31).

The object of the invention is to provide a novel use of the hydroxycitric acid compound and a novel method for using a garcinia extract containing the hydroxycitric acid compound for obtaining increased exercise endurance. (Spec., p. 2, l. 4-7).

Hydroxycitric acid is a known compound, at least in part, by its presence in the pericarps of trees of the *Garcinia* genus. (Spec., p. 1, l. 9-12, 16-18; p. 3, l. 16-27; p. 4, l. 1-6). It is known to be useful in the therapy of obesity because of its ability to inhibit ATP citrate lyase, one of the enzymes involved in the pathway that synthesizes lipids from citric acid, to suppress the increase in body adipose. (Spec., p. 1, l. 12-16, 19-20; p. 2, l. 12).

It is also known that hydroxycitric acid suppresses lipid synthesis by inhibiting ATP citrate lyase and, hence, promotes glycogen synthesis, causing an accumulation of glycogen in the liver, [Federation Proceedings, Vol. 44, No. 1, 139-144 (1985), Life Sciences, Vol. 53, No. 24, 1833-1845 (1993)]. No correlation has been found between accumulated liver glycogen and exercise endurance. (Spec., p. 1, l. 19-23; p. 2, l. 1-3)([e.g. Dohm G.L. et al., J. Appl. Physiol., 61, 1363-1368 (1986), 55, 830-833 (1983)]).

The inventors have discovered that hydroxycitric acid, in addition to having a body adipose increase-inhibitory action, has an exercise endurance-enhancing action. (Spec., p. 2, l. 8-12). The fact that the increase in body adipose is inhibited leads one to the logical supposition that the sources of energy for the muscles are curtailed. It was thus surprising to the inventors to discover that hydroxycitric acid showed an exercise endurance *enhancing* action rather than one that would adversely affect exercise endurance. (Spec., p. 2, l. 12-16).

The preferred hydroxycitric acid compound includes (-) – hydroxycitric acid and water soluble salts of (-) – hydroxycitric acid. The sodium or potassium salts are preferred species of the salt, although the salt of the hydroxycitric acid compound is not limited to alkali salts. (Spec., p. 3, l. 1-2, 9-15). The exercise endurance enhancer of this invention (hereinafter referred to as the "enhancer") is preferably an enhancer containing as the active ingredient (-) – hydroxycitric acid or a water-soluble salt of (-) – hydroxycitric acid as the active ingredient. (Spec., p. 3, l. 3-6). Particularly preferred is the non-salt form (-) – hydroxycitric acid which is not in salt form. (Spec., p. 3, l. 7-8).

The garcinia which contains hydroxycitric acid includes but is not limited to Garcinia cambogia, Garcinia indica, and Garcinia atroviridis. (Spec., p. 4, l. 10-12). Extracts from these sources are known and can be used directly as the enhancer of the invention. (Spec., p. 4, l. 13-14). Illustrative extracts include Garcinia Extract S (tradename, manufactured by Nippon Shinyaku Co., Ltd.), Garcinia Powder S (tradename, manufactured by Nippon Shinyaku Co., Ltd.), Citrin (tradename,

manufactured by Sabinsa (USA)) and Citrimax (tradename, manufactured by Interhealth (USA)), all of which are commercially available. (Spec., p. 4, l. 13-20).

The known extracts can be formulated with a suitable excipient, such as but not limited to food ingredients and food additives or a food containing the enhancer of the invention (hereinafter referred to as the food of the invention). (Spec., p. 4, l. 21-24). These food ingredients and additives include but are not limited to carbohydrates (sugars and sugar alcohols), sweeteners, acidulants, antioxidants, shelf-life extenders, and preservatives. (Spec., p. 4, l. 21-29; p. 5, l. 1-3, 7-25; p.6, l. 1-15). Vitamins, amino acids, minerals, a thickener-stabilizer, colors, diet fiber, a flavor, an emulsifier, a pH control agent, etc., can be formulated in suitable amounts with the above extracts. (Spec., p. 5, l. 3-6; p. 6, l. 16-21; p. 7, l. 1-9).

The enhancer of the invention can also be provided in combination with various health food materials and foods. (Spec., p. 7, l. 10-28; p. 8, l. 1,2; p. 9, l. 17-31).

The daily intake, in adult humans, of hydroxycitric acid in the method of the invention is dependent on the individual, (although preferably 250 mg-1.5 g), and the timing of ingestion, with the timing of ingestion taking place preferably during the last 30 minutes to 1 hour before a meal or immediately after an exercise. (Spec., p. 8, l. 3-14).

The exercise endurance enhancing effect of hydroxycitric acid was evaluated by measuring the swimming time of mice and the maximum oxygen uptake capacity in humans.

In an experiment measuring the swimming time of mice, the HCA-dosed group (administered 100 μL each day of (-) – hydroxycitric acid solution consisting of a 5 % weight concentration of free HCA) showed a significant enhancement of exercise endurance capacity over the control group (administered 100 μL each day of distilled water). (Spec., p. 9, l. 32-41; p. 10, l. 1-21, 30-32). The maximum swimming time of the HCA-dosed group exceeded the swimming time of the control group by approximately 24 minutes. Table 3 illustrates the results of the exercise endurance enhancing effect in mice. (Spec., p. 10, l. 23-29).

The exercise endurance enhancing effect in humans was evaluated by measuring the change in the maximum oxygen uptake capacity of a 42 year-old male subject administered 4 tablets, 3 times a day before each meal for 7 days. (Spec., p. 10, l. 34-35; p. 11, l. 6-9). Each tablet contained 62.5 mg of HCA (totaling 750 mg of HCA administered daily). (Spec., p. 11, l. 7-9). The maximum oxygen uptake capacity is a known parameter of exercise endurance, representing aerobic ATP generating activity such that an increase in the maximum oxygen uptake capacity represents an increase in exercise endurance. (McArdle, W. D., Katch, V. I. and Pechar, G. S., Med. Sci. Sports, 5, 156-160, (1973)) (Spec., p. 10, l. 34-35; p. 11, l. 1-5).

The results of the experiment revealed that administration of HCA caused a significant enhancement of exercise endurance. (Spec., p. 11, l. 20-26, 27-28). The male subject showed a 6.1 (ml/kg/min) increase in his maximum oxygen uptake capacity. (Spec., p. 11, l. 20-26, 27-28). Table 1 is illustrative of one recipe for tablets such as the ones administered in this experiment, (Spec., p. 8, l. 20-23; p. 9, l. 1-16),

and Table 4 illustrates the results of the exercise endurance enhancing effect in humans. (Spec., p. 11, l. 19-26).

ISSUES

I. Whether claims 24 to 31, 40 and 41 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 3,764,692 (Lowenstein) in view of U.S. Patent No. 5,536,516 (Moffett, et al.) and McCarty (45 Medical Hypotheses 247-54 (1995)).

GROUPING OF CLAIMS

Appellant concedes that the instant claims stand or fall together.

ARGUMENTS

I. The Examiner Has Rejected Claims 24 to 31 As Unpatentable Under 35 U.S.C. § 103(a) Due to Obviousness Over U.S. Patent No. 3,764,692 (Lowenstein) in view of U.S. Patent No. 5,536,516 (Moffett, et al.) and McCarty (45 Medical Hypotheses 247-54 (1995).

The Examiner argues that claims 24 to 31 are unpatentable over US '692 in view of US '516 and McCarty. (Off. Act. 07/06/00, p. 2, para. 5). The Examiner bases the rejection of the claims upon her conclusion that McCarty's hypothesis, though unsupported by experimental evidence, "discloses that hydroxycitric acid compositions from garcinia used for inducing weight loss *may* also be used to increase endurance." (Off. Act. 01/12/00, p. 6 to 7, para. 10). This disclosure, according to the Examiner, would have "motivated" an artisan of ordinary skill in the art "to use the hydroxycitric acid compositions taught by US '692 and US '516 in the method taught by McCarty."

A. The Examiner Concedes the References Cited Do Not Teach Use of (-) - Hydroxycitric Acid for Increasing Exercise Endurance.

While the Examiner alleges that McCarty shows HCA "may" be administered to increase exercise endurance, (Off. Act. 1/19/00, p. 6 to p. 7, para. 9), the Examiner concedes that the Lowenstein and Moffett references do not teach use of (-) - hydroxycitric acid for increasing athletic endurance: "These references teach the claimed hydroxycitric acid compositions, but they do not teach administering the compositions for increasing endurance during exercise." (Off. Act. 1/19/00, p. 6, para. 10).

Despite the Examiner's recognition that the prior art does not teach use of hydroxycitric acid compositions in the manner offered by the inventors, the Examiner nonetheless argues, without explanation or support, that "an artisan of ordinary skill would have been motivated to use the hydroxycitric acid compositions taught by US '692 and US '516" in combination with the "method taught by McCarty." (Off. Act. 1/19/00, p. 6, para. 10). The Examiner justifies her position by stating McCarty "provides a strong enough case for hydroxycitric acid increasing endurance (sic.) that a person of ordinary skill in the art would have reasonably expected that hydroxycitric acid would increase endurance." (Off. Act. 1/19/00, p. 6, para. 10).

B. Failure to Articulate What is Asserted as General Knowledge to Negate Patentability by the Examiner is An Improper Agency Action.

Appellant urges that the Examiner's rejection of the claims on appeal is based on nothing more than the Examiner's subjective belief. Rejection upon these grounds is clearly improper. See e.g., In re Sang Su Lee, No. 00-1158, 2002 WL 77144, at *4 (Fed.Cir. January 18, 2002) ("This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority."); In re Kotzab, 217 F.3d 1356, 1371, 55 USPQ2d 1313, 1317 (Fed.Cir. 2000) ("particular finding must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected theses components for combination in the manner claimed"); Brown & Williamson Tobacco Corp. v. Phillip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed.Cir.2000).

In In re Sang Su Lee, the Federal Circuit reversed the Board's decision to sustain the examiner's rejection of the claims, holding that both the Board and the examiner had erred in failing to adequately support the selection and combination of references which were found to render as obvious the invention Lee described. Id., 2002 WL 77144, at *3. "It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.' " Id., 2002 WL 77144, at *4, (citing W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312, 13 (Fed.Cir.1983)). The Federal Circuit based its decision on the obligation of Federal Agencies, found in the Administrative Procedures Act, to articulate a satisfactory explanation for its action. In re Sang Su Lee, 2002 WL 77144, at *4, (citing, Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 43(1983). Neither the board nor the examiner may "rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies." In re Sang Su Lee, 2002 WL 77144, at *6.

As is the case in the present appeal, an "[o]mission of a relevant factor required by precedent is both legal error and arbitrary agency action." Id., at *5.

C. The Examiner's Determination Of Obviousness From Her Combination of References Without a Particular Finding Is Legal Error.

In support of her combination of references, the Examiner argues that "[t]he hypothesis set forth by McCarty is backed up by strong reasoning based on the literature in the art at the time the article was written." (Off. Act. 6/22/00, p. 2, para. 5). The

Examiner, however, fails to provide any such reference or evidence from literature on which she relies. Nor does the Examiner provide a source for the teachings, suggestions or motivation, other than that provided by the inventors, which would have led to this combination of references or teachings. In re Sang-Su Lee, 2002 WL 77144, at *5.

D. The Examiner Has Failed to Present a Prima Facie Case of Obviousness Due to the Fact the Examiner's Combination of References Consists of Those Which Do Not Teach Use of (-) - Hydroxycitric Acid for Increasing Exercise Endurance.

Generally, the examiner must make out a prima facie case of unpatentability. See In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed.Cir.1988). The Examiner "has the burden under section 103 to establish a prima facie case of obviousness." Id., citing In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed.Cir.1984). The only manner in which the Examiner can satisfy this burden is by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art which would lead that person to combine the relevant teachings of the references. MPEP 2143; In re Fine, 837 F.2d at 1071, citing In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed.Cir.1984); see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 n. 24, 227 USPQ 657, 667 n. 24 (Fed.Cir.1985); ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir.1984).

The Examiner has relied on three references to support the rejection of the claims on appeal as obvious, two of which the Examiner has conceded do not teach use of (-) – hydroxycitric acid for increasing exercise endurance. In doing so, not only has the Examiner failed to provide sufficient justification to support the combination of the Lowenstein and Moffett references with McCarty, she makes use of the very references she has conceded do not teach the use of (-) - hydroxycitric acid (HCA) for increasing athletic endurance.

The Examiner states Appellant's reliance on Dohm are "contrary to common sense" and are "arguably" more likely to be dismissed than the "well-reasoned and well-supported" hypothesis of McCarty. These conclusory statements that "common sense" would have led one of ordinary skill in the art to use the hypothesis proposed by McCarty cannot work as a "substitute for authority when the law requires authority." In re Sang-Su Lee, 2002 WL 77144, at *5. The Examiner has failed to provide the required authority in support of the determination of obviousness. The Examiner has thus failed to establish a prima facie case of unpatentability and erred in her rejection of claims 24 through 31, 40 and 41 as obvious.

II. The Examiner's Reliance on McCarty Is Misplaced and Unsupportable.

The Examiner argues McCarty provides a "strong enough case" to lead one skilled in the art to expect HCA to increase exercise endurance. (Off. Act. 6/22/00, p. 3, para. 5). The Examiner summarily dismisses Dohm for its failure to specifically discuss

the effects of HCA on exercise endurance. (Off. Act. 8/21/00, p. 2, para. 2). Reliance on McCarty's hypothesis is logical and Appellant's reliance on Dohm is not, according to the Examiner, as Dohm's conclusions are "contrary to common sense" and are "arguably" more likely to be dismissed than McCarty's "well-reasoned and well-supported" hypothesis "[d]espite the fact that McCarty does not actually provide experimental evidence of this point." (Off. Act. 08/21/00, p. 2, para.2; Off. Act. 06/22/00, p. 2, para.5).

Appellant respectfully disagrees with this interpretation of McCarty and Dohm.

A. McCarty's Hypothesis Is Groundless.

McCarty's hypothesis poses that because HCA inhibits citrate lyase, HCA will reduce the generation of acetyl CoA in the liver, thus complementing the ability of glucagon to promote gluconeogenesis. McCarty further hypothesizes that glycogen is accumulated in the liver and this accumulation *may* aid aerobic endurance.

Dohm, on the other hand, teaches that increased fatty acid utilization, which results from lower glycogen levels in the liver, promotes aerobic endurance. Thus, although Appellant agrees that one skilled in the art could imagine that promoting gluconeogenesis may enhance exercise endurance, Dohm teaches that McCarty's hypothesis is groundless. The fact that Dohm does not mention HCA is irrelevant to Dohm's conclusion.

B. McCarty's Hypothesis Fails to Understand the Functioning of HCA and Would Not Reasonably Lead One Skilled in the Art to Use (-) - Hydroxycitric Acid for Increasing Exercise Endurance.

Appellant notes McCarty's selective use of references, in particular Brunengraber, et al., 82 Eur. J. Biochem. 373-84 (1978), cited as Reference No. 48 by McCarty. This article explains that the administration of HCA to livers of fed rats increased the concentrations of the glycolytic intermediates glucose 6-phosphate and fructose 6-phosphate, while decreasing the concentrations of all other intermediates. These results are convincing because HCA, by promoting the accumulation of citric acid, inhibits the enzyme phosphofructokinase. Thus, any glucose produced by the action of HCA will not enter into the TCA cycle via glycolysis due to the inhibition of phosphofructokinase by HCA. Therefore, even if glucose is produced by gluconeogenesis, that glucose is not available as an energy source and cannot enhance exercise endurance. (Spec., p. 1 to p. 2).

Those skilled in the art of biochemistry will realize that McCarty focuses only on one aspect of the function of HCA, and that his arguments are speculative. McCarty's paper is based on an incomplete understanding of the functioning of HCA, and would not teach one skilled in the art to reasonably expect that HCA would increase exercise endurance. One of ordinary skill in the art therefore would not be motivated to use the HCA compositions in the method taught by McCarty.

C. The Examiner Has Failed to Establish a Prima Facie Case of Obviousness in Under McCarty.

As stated previously, the Examiner has the burden to establish a prima facie case of obviousness and to do so must show some objective teaching or knowledge in the prior art which would lead one of ordinary skill in the art to combine the relevant teachings of the references. MPEP 2143; In re Fine, 837 F.2d at 1071, citing In re Lalu, 747 F.2d, at 705, 223 USPQ, at 1258; see also Ashland Oil, 776 F.2d, at 297 n. 24, 227 USPQ, at 667 n. 24.

This the Examiner has not done. The Examiner has failed to show how McCarty's hypothesis would teach that HCA would enhance aerobic endurance. (Off. Act. 6/22/00, p. 2 to p. 3, para. 5). This key problem in the Examiner's argument arises because McCarty's teachings are based on an incomplete understanding of how HCA functions. The McCarty paper hypothesizes that (1) HCA reduces the generation of acetyl CoA in the liver by inhibiting citrate lyase; (2) this reduced acetyl CoA compliments the ability of glucagon to promote gluconeogenesis; and (3) the accumulation of glycogen in the liver may aid aerobic endurance. These teachings of McCarty, in light of the art at that time, would not lead a person of ordinary skill in the biochemical arts to conclude that increased endurance of fasted rats is likely to be the result of increased fatty acid oxidation and the sparing of muscle glycogen. (Spec., p. 2). This interpretation of McCarty flies in the face of contrary teachings in the prior art.

Appellant urges that the Examiner has failed to show that the prior art cites the uses for HCA as suggested by the Examiner. Moreover, the Examiner concedes that Lowenstein and Moffett do not teach the use of (-) - hydroxycitric acid (HCA) for increasing athletic endurance. Finally, the Examiner fails to cite any evidence to support her assertion that it is obvious in light of the prior art to use HCA for exercise endurance.

III. The Expert Declaration of Dr. Tohru Fushiki Rebuts the Arguments Made by the Examiner and Presents Evidence That the Invention is Not Obvious in Light of McCarty.

Assuming, *arguendo*, that the Examiner has met the burden under section 103 to establish a prima facie case of obviousness, Appellant submits that the 37 C.F.R. 1.132 Declaration of Dr. Tohru Fushiki, one of the inventors of the present application, rebuts any possible prima facie case. Dr. Fushiki's curriculum vitae is included with the Declaration and the Examiner has never challenged Dr. Fushiki's credentials as an expert in the pertinent art area.

A. Dr. Fushiki is an Expert in the Field of Nutritional Chemistry and Qualified to Provide Evidence With Regard to the Skill in the Art and Non-obviousness of the Invention.

Dr. Tohru Fushiki, Ph.D. in Agriculture, is currently a Professor of Nutritional Chemistry at Kyoto University and is the principal author or co-author of approximately 90 publications in nutritional chemistry. (See Dec., Exibit A, p. 1 – 8). Dr. Fushiki

possesses knowledge of one with ordinary skill in the art, knowledge in the art of biochemistry, especially as it relates to nutritional chemistry, and has followed and continues to follow the scientific literature regarding the development of foods that increase or enhance exercise endurance. (Dec. p. 1 to p. 2, para. 7). The evidence of record establishes that Dr. Fushiki is an expert in the field of nutritional chemistry and is fully qualified to provide probative evidence in regard to this matter.

B. Failure By the Examiner to Accord the Requisite Weight to an Expert's Declaration is Reversible Error.

The Examiner has failed to give any weight to Dr. Fushiki's declaration. It is well settled law that an Examiner's failure to accord any weight to an expert's declaration is reversible error. In re Alton, 76 F.3d 1168, 1174 (Fed.Cir.1996) ("[t]he examiner also erred by dismissing the Wall declaration without an adequate explanation of how the declaration failed to overcome the prima facie case initially established by the Board,..."); see also Ex Parte Brault, *et. al.*, Appeal No. 97-0222, 1997 WL 1883820, at *2 (Bd. Pat. App. & Inerf.).

Declaration evidence presented by the Appellant must be accorded its fair weight. It is reversible error on the part of an Examiner to dismiss the declaration with such indifference. Ex Parte Cunningham, *et al.*, Appeal No. 95-3055, 1995 WL 169272 at *3, (Bd. Pat. App. & Inerf.)("It is not understood how a statement by an expert as to what skilled artisans would have interpreted a term of art to mean is '[p]urely conclusory.'"); Ex Parte Tanksley, 37 USPQ 2d 1382, 1385 (Bd.Pat.App.&Interf. 1994)

("[t]he declaration evidence is entitled to fair weight and, in our judgment, the Examiner erred by (1) characterizing Murray's analysis as 'merely hypothetical,' and (2) summarily dismissing the declaration as containing 'unsupported opinions.' "); see also Ex Parte Ovshinsky, 10 USPQ2d 1075, 1077 (Bd. Pat. App. & Interf. 1989); Cseh et al. v. Forter et al., 209 USPQ 1118, 1120 (Com'r Pat. & Trademarks 1980). The afore mentioned authority cannot be dispensed with. The precedent requires that declaration evidence be allotted its fair weight in an Examiner's analysis of the claims in light of the prior art.

C. The Examiner Erred by Not According the Proper Weight to the Declaration.

In this case the Examiner has clearly erred. The Examiner failed to address any of the facts presented in Dr. Fushiki's testimony and has accorded the Fushiki Declaration little, if any, weight. The Examiner referred to Dr. Fushiki's evidence only in passing, dismissing the declaration without addressing the reasoning or factual basis therein. (Off. Act. 12/03/01, p. 2). Such offhanded dismissal of a proffered expert opinion, according to the Board, is clearly improper.

> The affidavit establishes [the declarant] as an expert in this field, and this is not gainsaid by the examiner. It is not understood how a statement by an expert as to what skilled artisans would have interpreted a term of art to mean is "[p]urely conclusory." The "factual basis" for the conclusion as to what a particular term means is clearly the expert's experience and education in the field.

Ex Parte Cunningham, *et al.*, Appeal No. 95-3055, 1995 WL 169272 at *3, (Bd. Pat. App. & Inerf.). An Examiner's failure to give any weight to the opinion of an expert's testimony is clearly objectionable and subject to reversal. The Examiner's failure in this instance to accord any weight to the expert's

declaration and summarily disregard the declaration without a proper proffer of evidence to support her conclusions is clear error.

D. Dr. Fushiki's Declaration Explains Why McCarty's Hypothesis is Incorrect.

In his Declaration, Dr. Fushiki provides expert testimony of one skilled in the prior art. Dr. Fushiki explains that McCarty's hypothesis is incorrect, as it is not the increased glycogen levels hypothesized by McCarty, but the lower glycogen levels in the liver which enhance exercise endurance, as explained by Dohm. (Dec., p. 4, para. 17).

Dr. Fushiki's declaration fully addresses the fact that McCarty's hypothesis is based on an incomplete understanding of how HCA functions. As previously mentioned, McCarty hypothesizes that (1) HCA reduces the generation of acetyl CoA in the liver by inhibiting citrate lyase; (2) this reduced acetyl CoA compliments the ability of glucagon to promote gluconeogenesis; and (3) the accumulation of glycogen in the liver may aid aerobic endurance. This hypothesis is offered without support of experimental data and a selective reliance of references. As explained by Dr. Fushiki, McCarty's hypothesis, in light of the art at that time, would not have lead a person of ordinary skill in the biochemical arts to conclude that increased fatty acid oxidation and the sparing of muscle glycogen would result in increased endurance of fasted rats. (Dec. p. 2 to p. 3, para. 11-16). By relying on faulty reasoning, the Examiner has incorrectly concluded the present invention is obvious in light of the prior art.

E. Dr. Fushiki's Declaration Supports the Conclusion That Use of Hydroxycitric Acid as an Exercise Endurance Enhancing Agent is Not Obvious.

Dr. Fushiki's declaration provides a solid evidence that use of hydroxycitric acid as an exercise endurance enhancing agent is not obvious, as argued by the Examiner, in light of McCarty. (Dec. p. 2 to p. 4). The Examiner argues that because Dohm sets forth no data concerning hydroxycitric acid, a person of ordinary skill would not be able to conclude from Dohm that the hypothesis stated by McCarty is incorrect. (Off. Act. 6/28/00, p. 3, para. 5). Dr. Fushiki, however, explains that although one of ordinary skill could have envisioned the promotion of gluconeogenesis may enhance exercise endurance in light of McCarty, Dohm teaches such a hypothesis is groundless when it is the lower glycogen levels in the liver and not the increased glycogen levels hypothesized by McCarty, which enhance aerobic endurance. (Dec., p. 4, para. 17).

The teachings of Brunengraber provide that the administration of HCA to livers of fed rats increases the concentrations of glycolytic intermediates glucose-6-phosphate and fructose 6-phosphate and decreases the concentrations of all other intermediates. This is consistent with what is known in the art regarding HCA's inhibition of the enzyme phosphofructokinase, which is the key enzyme in the control of glycolysis. (Dec., p. 4, para. 18 to para. 20).

Both a high level of ATP and HCA inhibit phosphofructokinase, ATP by decreasing phosphofructokinase's affinity for fructose-6-phosphate and HCA by promoting the accumulation of citric acid. (Dec., p. 4, para. 20 to para. 21). Citrate

enhances ATP's inhibitory effect on phosphofructokinase. (Dec., p. 4, para. 20). Because HCA functions to inhibit phosphofructokinase by promoting the accumulation of citric acid, it prevents any glucose produced by the action of HCA from entering into the citric acid cycle via glycolysis, so that even if glucose is produced during gluconeogenesis, it is not available as an energy source and cannot enhance exercise endurance. (Dec., p. 4, para. 21 to para. 22).

Dr. Fushiki's declaration clearly sets out the faults in McCarty as well as the relevance and support found in Dohm. (Dec. p. 2 to p. 4). Dr. Fushiki states that although one of ordinary skill could have envisioned the promotion of gluconeogenesis may enhance exercise endurance in light of McCarty, Dohm teaches such a hypothesis is unsupported by the art, as it is lower glycogen levels in the liver, not the increased glycogen levels hypothesized by McCarty, which enhance aerobic endurance. (Dec., p. 4, para. 17).

Thus, in view of Dr. Fushiki's Declaration and the above remarks, Appellants urge that claims 24-31 are not obvious in light of Lowenstein, Moffett, and McCarty, and respectfully request reconsideration and withdrawal of this rejection.

IV. Claims 40-41 are Allowable as Dependant on Claims 24-25.

Appellant has canceled claims 32-39 and added claims 40-41 reciting food as a limitation on the composition of claims 24-25. Claims 40-41 are dependent on claims 24-25, and are therefore allowable for at least the reasons that claims 24-25 are allowable.

CONCLUSION

The Examiner's position that Claims 24 to 31, 40 and 41 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 3,764,692 (Lowenstein) in view of U.S. Patent No. 5,536,516 (Moffett, et al.) and McCarty (45 Medical Hypotheses 247-54 (1995) is unsupported by the evidence. Dr. Fushiki's Declaration and the above analysis of the theories relied upon by the Examiner demonstrate that claims 24-31, 40 and 41 are not obvious in light of Lowenstein, Moffett, and McCarty. Appellant urges that the rejection of claims 24 to 31, 40 and 41, under § 103 is legally and factually incorrect. Reconsideration by the Examiner of the rejection of the claims under § 103 and withdrawal of this rejection is urged by Appellant. In the event that the Examiner maintains the rejections of record, Appellant respectfully requests the Board to reverse the Examiner's rejections.

Respectfully submitted,

Greenberg Traurig LLP

Date: February 21, 2002

By: _____
EUGENE C. RZUCIDLO
Attorney for Appellants
Registration No. 31,900

GREENBERG TRAURIG LLP
885 Third Avenue, 21st Floor
New York, NY 10022-4834
(212) 848-1000

APPENDIX

WHAT IS CLAIMED IS:

24. A method of enhancing exercise endurance in a subject undertaking exercise comprising administering to the subject a composition comprising (-)-hydroxycitric acid or a lactone form thereof, or a salt thereof, as active ingredient.

25. A method of enhancing exercise endurance in a subject undertaking exercise comprising administering to the subject a composition comprising (-)-hydroxycitric acid or a water-soluble salt of (-)-hydroxycitric acid as active ingredient.

26. The method of claim 24 wherein the active ingredient originates from an extract of garcinia pericarps containing (-)-hydroxycitric acid or a lactone form thereof, or a salt thereof.

27. The method of claim 25 wherein the active ingredient originates from an extract of garcinia pericarps containing (-)-hydroxycitric acid or a lactone form thereof, or a salt thereof.

28. The method according to claim 26, wherein the garcinia is Garcinia cambogia, Garcinia indica or Garcinia atroviridis.

29. The method according to claim 27, wherein the garcinia is Garcinia cambogia, Garcinia indica or Garcinia atroviridis.

30. The method according to claim 25 wherein the water-soluble salt of (-)-hydroxycitric acid is the sodium salt or the potassium salt.

31. The method according to claim 27, wherein the water-soluble salt of (-)-hydroxycitric acid is the sodium salt or the potassium salt.

40. The method of any one of claims 24-31 wherein the composition further comprises a food.

41. The method of claim 40, wherein the food is a confection, a drink, a sport food, a sport drink, a health food, a seasoning, a food ingredient, a noodle, a bakery food, a cereal food or a retort food.

CERTIFICATE OF MAILING

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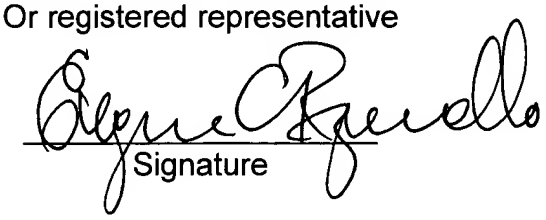
Eugene C. Rzucidlo
Name of Appellant, assignee
Or registered representative



Signature

February 21, 2002
Date of Signature